

**BOSENTAN- bosentan tablet, for suspension**  
**Zydus Lifesciences Limited**

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**Bosentan Tablets for Oral Suspension**

**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

NDC 70771-1908-8

Bosentan Tablets for Oral Suspension, 32 mg

PHARMACIST: Dispense the accompanying Medication Guide to each patient.

Phenylketonurics: Contains Phenylalanine 2.08 mg per tablet for oral suspension.

56 Tablets (4 x 14 unit-dose)

Rx only

Zydus



## BOSENTAN

bosentan tablet, for suspension

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:70771-1908
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>BOSENTAN</b> (UNII: Q326023R30) (BOSENTAN ANHYDROUS - UNII:XUL93R30K2)	BOSENTAN ANHYDROUS	32 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>ACESULFAME POTASSIUM</b> (UNII: 23OV73Q5G9)	
<b>ASPARTAME</b> (UNII: Z0H242BBR1)	
<b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>DIMETHYLAMINOETHYL METHACRYLATE - BUTYL METHACRYLATE - METHYL METHACRYLATE COPOLYMER</b> (UNII: 905HNO1SIH)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MANNITOL</b> (UNII: 3OWL53L36A)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	

### Product Characteristics

<b>Color</b>	WHITE (off-white to pale yellow)	<b>Score</b>	2 pieces
<b>Shape</b>	ROUND	<b>Size</b>	10mm
<b>Flavor</b>	TUTTI FRUTTI	<b>Imprint Code</b>	1508
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1908-8	4 in 1 CARTON	02/17/2026	
1	NDC:70771-1908-7	14 in 1 BLISTER PACK; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA213981	02/17/2026	

**Labeler** - Zydus Lifesciences Limited (918596198)

### Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		863362789	ANALYSIS(70771-1908) , MANUFACTURE(70771-1908)